United States Court of Appeals
for the
District of Columbia Circuit

REPLY
BRIEF

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

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For the District of Columbia Circuit

FILED JUL 12 1985

GEORGE A. FISHER
CLERK

No. 84-1252 & No. 85-1014

PUBLIC CITIZEN HEALTH RESEARCH GROUP, et al.,

Petitioners,

v.

ROBERT A. ROWLAND, Assistant Secretary of Labor,
Occupational Safety and Health Administration, et al.,

Respondents.

On Petitions for Review to the
Occupational Safety and Health Administration

REPLY BRIEF OF PETITIONERS

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July 12, 1985

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PETITIONERS' REPLY BRIEF

Introduction and Summary of Argument

In their opening brief, petitioners demonstrated that the scientific evidence conclusively establishes that ethylene oxide ("EtO") poses a serious risk of cancer, genetic damage, and spontaneous abortions to the 140,000 workers who are exposed to EtO. Petitioners also demonstrated that, prior to the June 15 intervention by the Office of Management and Budget ("OMB"), respondents had determined that a short-term exposure limit ("STEL") was an integral component of the revised EtO standard. In fact, they had concluded that, without a STEL, workers would be subjected to a "significant risk" of cancer and would be left largely unprotected from the risks of genetic damage and spontaneous abortions.

Respondents had also determined that a STEL would be "feasible" and would "significantly augment" the protection afforded by the other provisions of the revised standard.

Remarkably, respondents' defense of their overnight decision to delete the STEL fails to address the key arguments raised in petitioners' opening brief. Indeed, respondents have engaged in nothing less than a legalistic game of hide and seek, ignoring petitioners' principal arguments and discussing at length matters not at issue.

As we demonstrate in Point I below, respondents never reply to petitioners' contention that the deletion of the STEL is at odds with the OSH Act and not supported by substantial evidence. In fact, respondents avoid altogether discussing petitioners' chief argument -- that the deletion of the STEL cannot be reconciled with OSHA's repeated findings that its final standard does not eliminate the significant cancer risk posed by EtO, and that a STEL would further reduce that risk. Compare Petitioners' Opening Brief ("Pet. Br.") at 16, 36-37, with Respondents' Brief ("Resp. Br.") at 47-53. Nor does OSHA confront its prior findings that a STEL is essential to minimize the serious risks of genetic damage and spontaneous abortions that workers will face even with a 1 ppm 8-hour limit in effect. Compare Pet. Br. at 17-22, 37-38, with Resp. Br. at 47-53. And OSHA entirely ignores petitioners' claim that OSHA has completely shifted its position from that taken in its June 14th Document by arguing that a 1 ppm standard will necessarily force employers to reduce short-term exposures significantly. Compare Pet. Br. at 47-50, with Resp. Br. at 52-53.

OSHA's defense to petitioners' claim of improper OMB interference is no more to the point, as is demonstrated in Point II. Most of OSHA's attention is devoted to arguing that Executive Order 12291 is constitutional on its face and that the President has the power to remove the Secretary of Labor at his discretion -- points petitioners have never disputed. However, respondents failed to articulate a theory under which OMB is properly authorized to exercise *de facto* veto power over the legislative determinations which Congress has entrusted to the Secretary of Labor. Nor have respondents grappled with petitioners' contention that OMB's intrusion is particularly egregious here since the Executive Order mandates consideration of cost-benefit principles that are at odds with the criteria that Congress intended to govern OSHA rulemakings.

As is evident, the deletion of the STEL is neither supported by substantial evidence nor the product of reasoned decisionmaking. Moreover, this rulemaking has been tainted by OMB's impermissible interference with the legislative functions assigned by Congress to the Secretary of Labor. For these reasons, the decision to delete the STEL should be set aside, and respondents should be directed to issue the short-term exposure limit contained in the June 14 Document without delay.

I. THE DELETION OF THE STEL IS NOT SUPPORTED BY THE RECORD AND CONTRAVENES THE OSH ACT.

In petitioners' opening brief, we pointed to three findings by OSHA which, when analyzed together, required OSHA to include a STEL in its revised EtO standard. First, OSHA has repeatedly stated that "all of the [risk] assessments indicated that the excess cancer risk from EtO exposure at 1 ppm over a working lifetime are significant [and that] . . . OSHA has determined that a significant risk is not eliminated by lowering the TWA to 1 ppm." Preamble to OSHA's Final Standard, 49 Fed. Reg. 25734, at 25765 (App. at 459)(emphasis in original); see also id. at 25773 (App. 467). Second, the agency has consistently acknowledged that "OSHA must, if it is feasible, seek to reduce [the cancer] risks below those estimated by the risk assessment to persist at a PEL of 1 ppm." Preamble at 25766 (App. 460). And third, OSHA has expressly found that a STEL would be economically and technologically feasible, and that "compliance with a 10 ppm, 15-minute STEL will significantly augment the employee protection provided" by other portions of the standard. June 14th Document at 172-73, 218 (App. 183-84, 229).

In light of these findings, and the clear mandate of the Act, which directs OSHA to "set the standard which most adequately assures, to the extent feasible, that no employee will suffer material impairment of health . . .", 29 U.S.C. § 655(b)(5), American Textile Manufacturers Institute v. Donovan ("ATMI v. Donovan"), 452 U.S. 490, 509, 540 (1981), petitioners contended that OSHA had no option but to include a STEL in its final standard. Pet. Br. at 37-39. Petitioners further argued that the necessity for a STEL was significantly bolstered by OSHA's conclusions in its June 14th Document, which emphasized that a STEL was essential to protect workers from the serious genetic and reproductive effects associated with short-duration exposures to EtO. Pet. Br. at 17-21; see also Preamble at 25747 (App. 441)(genetic damage in humans occurs at "exposure concentrations of 1 ppm or less").

Despite the significance of the June 14th Document, OSHA does not mention it at all, much less attempt to explain why the considerations it sets forth supporting the inclusion of a STEL are no longer well-founded. Rather, OSHA's brief simply paraphrases its December 19 decision not to go ahead with a STEL. Compare Resp. Br. at 47-53 with App. 536-49. Although the flaws in OSHA's decision rejecting the STEL, which are spelled out in detail in petitioners' opening brief at pages 40-50 will not be repeated here, there are two points raised in respondents' brief that warrant a reply.

A. The standard does not satisfy the requirements of the OSH Act that significant occupational health risks must be reduced to the lowest feasible level. 29 U.S.C. § 655(b)(5). OSHA does not contest that a significant cancer risk persists even with its 1 ppm standard in place. See, e.g., Preamble at 25766 (App. 460); Resp. Br. at 43, 44 & 60. However, it attempts to sidestep the issue by arguing that the 1 ppm limit will "substantially reduce" the risk to workers. Resp. Br. at 46, 51.

According to OSHA, the residual risk is acceptable because OSHA has lowered EtO exposures "to the extent feasible" through the 8-hour limit. Resp. Br. at 54, 60. Thus, despite the persistence of significant cancer risk at the new PEL, OSHA concluded that "the record does not demonstrate the inadequacy in the protection provided by the PEL due to the lack of a STEL." Resp. Br. at 51. OSHA's justification is riddled with flaws and cannot withstand scrutiny.

To begin with, OSHA has not lowered exposures to the extent feasible, even though it has acknowledged that it "must, if it is feasible, seek to reduce the risks below those . . . [which] persist at a PEL of 1 ppm." Preamble at 25766 (App. 460). OSHA has previously stated that "a STEL acts in conjunction with an 8-hour TWA to reduce employee exposures to significant risks," and "will significantly augment the employee protection provided by the 8-hour TWA." June 14th Document at 217-18 (App. 228-29). However, its brief makes no attempt to respond to, let alone rebut, its own prior findings.

OSHA's speculation that other protective provisions of the standard, such as monitoring and employee training, "will reduce the [residual] risk of cancer below the 1-2 in 1000 level projected in the risk assessment," Resp. Br. at 46, is similarly groundless. Not only does OSHA fail to support this assertion with any reference to the record, but it fails to explain why monitoring and employee training will have any bearing at all on short-term exposure patterns since neither of these provisions require employers to reduce exposure levels. Equally important, although OSHA tries to downplay the gravity of the risk which persists at 1 ppm, it neglects to mention that the agency has concluded that "the risk may be approximately five times larger" than that projected, and that the risk assessment conducted by the major industry group calculated an excess risk of "18 to 79 [cancer] deaths per 10,000 for on-the-job exposures of 1 ppm, approximately 1.5 to 3.3 times higher" than OSHA's estimate. Preamble at 25757, 25763 (App. 451, 457). Moreover, the risk assessments do not address the threats of spontaneous abortion and genetic damage, which OSHA has acknowledged are serious and largely unabated even with a 1 ppm standard in place. June 14th Document at 68-72, 83-84, 166, 217-22 (App. 79-83, 94-95, 177, 228-33). Thus, OSHA's attempt to minimize the risks workers face with the 1 ppm limit in effect cannot be squared with the record or with its opposite conclusion in the June 14th document.

2. OSHA's defense of the deletion of the STEL rests entirely on its claim that a STEL cannot be imposed without substantial evidence indicating that adverse health effects associated with EtO are dose-rate dependent. According to OSHA, the "central question underlying the possible need for a STEL was whether a dose-rate relationship has been demonstrated." Resp. Br. at 48. OSHA then goes on to contend that the deletion of the STEL was necessary because "no such

data exist at present." Resp. Br. at 49. This argument misses the mark for several reasons.

To begin with, OSHA's suggestion that "dose-rate relationship" was a "central question" in this proceeding is nothing less than revisionist history. OSHA had never expressed the need for dose-rate data in setting a ceiling limit or a STEL in any prior rulemaking. Indeed, neither OSHA, OMB, nor anyone else for that matter, raised the issue at OSHA's administrative hearing, in post-hearing comments, or even in OSHA's announcement extending the rulemaking on the STEL. Rather, the dose-rate issue surfaced in a comment filed during the rulemaking on the STEL, and the first time that OSHA ever mentioned the issue was in its December 19, 1984 decision rejecting the STEL. Thus, it is totally misleading for OSHA to suggest that the dose-rate effect issue was anything more than an afterthought, seized on by the agency to justify the decision -- made on June 15 -- to jettison the STEL.

Nor can OSHA's contention that no data showing a dose-rate relationship exist be squared with the record. Respondents' brief leaves entirely unanswered petitioners' contention -- supported by OSHA's own scientific staff and by NIOSH -- that data indicating a dose-rate relationship exist and are in the record. See Pet. Br. at 43-45. Respondents also fail to confront the fact that in the Preamble OSHA itself recognized a dose-rate relationship, Preamble at 25744 (App. 438)("EtO was found both to induce and inhibit DNA repair, depending on dose and exposure schedule") and that it relied heavily on the 1982 study which documented EtO dose-rate effects.[1] Respondents are not free simply to ignore record evidence that does not support their view. ATMI v. Donovan, supra, 452 U.S. at 522-23; see also Universal Camera Corp. v. NLRB, 340 U.S. 474, 477 (1951).

As part of its justification for refusing to issue a STEL, OSHA claims that further research on the dose-rate question is needed before OSHA can take action, and states that it requested NIOSH funding for additional work in this area. In so arguing, OSHA distorts the events surrounding its unsuccessful effort to persuade NIOSH to fund such a study. OSHA suggests that its request for funding became moot when Dr. Yager, the scientist who would have conducted the study, withdrew her proposal. Resp. Br. at 50-51 n.44; see also id. at 70. In fact, NIOSH had informed OSHA, well prior to the submission of OSHA's brief, that NIOSH saw no need to engage in further research on EtO's dose-rate effects, since there already was ample available evidence to support a STEL. See letter of March 19, 1985 from Dr. J. Donald Millar, Director of NIOSH, to Robert Rowland, Assistant Secretary for OSHA, which appears at A1 in the Addendum to this brief.

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[1] The study by Cummings, et al., [Ex. 2-37] discussed extensively in the Preamble, concluded that EtO had far more serious adverse effects on the repair of genetic damage in animals when the same cumulative dose of EtO was received over a shorter period of time than when it was spread over a longer period. See App. 726, at 741-42. While OSHA extensively relied on this study, OSHA's failure to discuss the study's findings in terms of "dose-rate" confirms petitioners' contention that this dose-rate argument was simply an afterthought developed during the final stages of the extended rulemaking. See Preamble at 25744, 25747 (App. 438, 441).

OSHA also never explains why it could not impose a STEL in the absence of dose-rate data, since never before or since has it required dose-rate data to support a STEL. On the contrary, OSHA has issued short-term limits in the past for precisely the kinds of reasons articulated in its June 14th Document and has recently published two proposed rules -- for asbestos and ethylene dibromide -- which include short-term limits but do not suggest that dose-rate data is necessary. See, e.g., 39 Fed. Reg. 35890 (1974)(vinyl chloride STEL); 43 Fed. Reg. 45762, 45775-76 (1979)(acrylonitile STEL); 48 Fed. Reg. 45956, 45976-81 (1983) (ethylene dibromide proposal); 49 Fed. Reg. 14117, 14123 (1984) (asbestos proposal). Moreover, OSHA has submitted to OMB for review a draft proposal for a revised benzene standard which also contains a STEL provision, but does not justify it on dose-rate grounds. (A copy of the portions of OSHA's benzene proposal relating to the STEL appear at pages A2-A12 of the Addendum to this brief). Thus, by all indications, this requirement was contrived solely for this rulemaking.

OSHA's argument that it would have been a departure from agency policy to impose a STEL "solely on the grounds that the TWA did not reduce the risk to the level of insignificance" is without foundation for several reasons. Resp. Br. at 93-94 (emphasis in original). First, although OSHA points to four rulemakings which it suggests support its contention that the agency has not in the past imposed a STEL simply to reduce significant risk, OSHA neglects to mention that all of the rulemakings (arsenic, cotton dust, lead, and benzene) were completed prior to the Supreme Court's decision in Industrial Union Department, AFL-CIO v. American Petroleum Institute ("Benzene"), 448 U.S. 607 (1980). The issue of "significant risk" did not come into play until the Benzene decision, and hence none of the agency's pre-1980 rulemakings sought to justify standard-setting in those terms. Moreover, since EtO is the only final health standard the agency has issued since 1980, it is difficult to understand how OSHA could have a "policy" relating to rulemaking on the basis of "significant risk" from which it could depart.

Second, in the three standards OSHA mentions that do not contain short-term limits, there are critical differences between those substances and EtO which render any attempted parallels worthless. With respect to arsenic, OSHA concluded in 1978 when it issued the standard that a short term limit would not be feasible and did not reconsider the issue in its limited rulemaking in 1983. See 43 Fed. Reg. 19600, 19613 (1978); 48 Fed. Reg. 1864, 1902-03 (1983). With respect to the 1978 lead and cotton dust standards, in neither case was there any suggestion that workers are exposed in short-term bursts, rather than continuously, and thus short-term limits were not at issue. 43 Fed. Reg. 27350 (1978)(cotton dust); 43 Fed. Reg. 52952 (1978), 46 Fed. Reg. 6134 (1981)(lead).

Third, OSHA's reliance on benzene is seriously misplaced. While OSHA contends that "in recent years the Agency has issued standards regulating toxic substances, including benzene . . . without a short-term limit," Resp. Br. at 93, that contention is false. The benzene standard presently in force was a consensus standard adopted by OSHA in 1971 under § 6(a) of the Act, 29 U.S.C. § 655(a), and contains a ceiling restricting high-dose exposures. 29 C.F.R. § 1910.1000 Table Z-2. Moreover, in its 1978 standard which was set aside by the Supreme Court, OSHA included a short-term limit. 43 Fed. Reg. 5918, 5943 (1978). And, as noted above, OSHA's recent draft proposal also contains a STEL. Thus, OSHA has consistently recognized the need for a short-term limit to control peak exposures to benzene.

* * * *

As is apparent, OSHA is attempting to construct an evidentiary requirement that, if accepted, could frustrate the goals of the OSH Act. OSHA concedes that a number of studies in the record have found serious, adverse health effects in workers intermittently exposed to EtO. Nevertheless, OSHA refuses to act, arguing it must await the results of further research.

Stripped to its essentials, OSHA appears to be arguing that even in the face of this record, it is free to claim scientific uncertainty, and throw up its hands and do nothing until definitive dose-rate evidence becomes available. That view, however, is at odds with the OSH Act. Congress directed

OSHA to act on the basis of the "best available evidence", 29 U.S.C. § 655(b)(5), precisely because it did not want OSHA to become paralyzed by this sort of debate. Indeed, this Court has recognized that OSHA "cannot let workers suffer while it awaits the Godot of scientific certainty." United Steelworkers of America v. Marshall, 647 F.2d 1189, 1266 (D.C. Cir. 1980), cert. denied, 453 U.S. 913 (1981). "OSHA's mandate necessarily requires it to act -- even if the information is incomplete -- when the best available evidence indicates a serious threat to the health of workers." AFL-CIO v. Marshall, 617 F.2d 636, 651 (D.C. Cir. 1979), aff'd in part, rev'd in part sub nom. ATMI v. Donovan, supra.

Accordingly, even if OSHA were correct that the evidence on the health effects attributable to short-term exposures is incomplete, that would not excuse its inaction in light of its own findings -- backed up by NIOSH and NIEHS -- that short-term exposures increase the risk of cancer, and cause genetic damage and spontaneous abortions.

II. OMB'S INTERFERENCE CONTRAVENES THE OSH ACT AND CANNOT BE JUSTIFIED AS A VALID EXERCISE OF PRESIDENTIAL POWER UNDER ARTICLE II OF THE CONSTITUTION.

In their opening brief, petitioners argued that OMB's last minute interference with the issuance of the EtO standard violated the OSH Act in two critical respects. First, petitioners contended that because the Act assigns sole decisional authority to the Secretary of Labor, and nothing in the Act or its legislative history suggests that Congress intended that

OMB play any role whatsoever, OMB's assumption of the Secretary's decisionmaking responsibility was improper. Second, petitioners argued that OMB's interference was unlawful because OMB compelled OSHA to overturn its decision to include a STEL on the basis of the strict cost-benefit analysis required by Executive Order 12291. As petitioners' explained, the OSH Act expressly directs OSHA to place "the 'benefit' of worker health above all other considerations," ATMI v. Donovan, supra, 452 U.S. at 509, and forbids the mechanical application of cost-benefit principles in standard-setting.

Respondents do not confront these arguments head-on. Rather, they argue that OMB's involvement did not violate the OSH Act because Congress, in passing the OSH Act, implicitly granted OMB the authority to supervise OSHA's rulemakings. Respondents also assert that OMB did not override the Secretary's decisionmaking authority, but rather the Secretary independently reached the decision to delete the STEL. As we demonstrate below, neither of these contentions is well-founded.

A. In petitioners' opening brief, we explained that Congress, in the OSH Act, expressly delegated sole responsibility for formulating occupational safety and health standards to the Secretary of Labor. See 29 U.S.C. § 651; Industrial Union Department v. Hodgson, 499 F.2d 467, 470, 474 (D.C. Cir. 1974). Congress did so because of the Labor Department's unique expertise in making the highly technical decisions, often on "the frontiers of scientific knowledge," that lie at the core of OSHA's standards. *Industrial Union Department v. American Petroleum Institute*, 448 U.S. 607, 656 (1980). And we noted that in promulgating health standards, the Secretary is acting as Congress' surrogate, engaging in fundamentally legislative activity. *See* Pet. Br. at 52-53.

These points are hardly open to question. Indeed, respondents acknowledge that OSHA rulemakings are "legislative" in character, and stress that "because of the Secretary's congressionally delegated role as a legislator and his status as expert in occupational safety and health," the Secretary's "legislative choice[s]" are entitled to deference from the courts. Resp. Br. at 16-17. Nonetheless, respondents' main argument is that in passing the OSH Act, Congress implicitly granted OMB the authority to second-guess the Secretary's judgments and to exercise "supervisory" power over OSHA rulemakings. Resp. Br. at 79-87.

In seeking to identify the source of OMB's power, respondents do not contend that there is anything in the OSH Act or legislative history which explicitly authorizes OMB's involvement. Nor do respondents claim that Congress has ever affirmatively taken any action to centralize this power in OMB, doubtlessly because Congress has repeatedly rejected such attempts. *See*, *e.g.*, Rosenberg, *Beyond the Limits of Executive Power: Presidential Control of Agency Rulemaking Under Executive Order 12291*, 80 Mich. L. Rev. 193, 221-25 (1981)(hereinafter "Rosenberg"); Olson, *The Quiet Shift of Power: Office of*

Management and Budget Supervision of Environmental Protection Agency Rulemaking Under Executive Order 12291, 4 Va. J. Nat. Resources L. 1, 24 (1984)(hereinafter "Olson"); see also 44 U.S.C. §§ 3504(h), 3518 (Paperwork Reduction Act's limitations on OMB's authority).

Rather, respondents claim that this power emanates from the President's constitutional duty to "take care that the laws be faithfully executed." U.S. Const., art. 2 § 3. As this Court has noted, to "ensure the President's control and supervision over the Executive Branch, the Constitution -- and its judicial gloss -- vests him with the powers of appointment and removal, the power to demand written opinions from executive officers, and the right to invoke executive privilege to protect consultative privacy." Sierra Club v. Costle, 657 F.2d 298, 405 (D.C. Cir. 1981)(footnote omitted). Respondents contend that these powers give the President the authority to exercise what is tantamount to a veto over the Secretary of Labor's determinations in OSHA rulemakings.

To accept respondents' argument, this Court would be required to rewrite constitutional law and to hold that the President's authority over his subordinates is virtually absolute, a result which would seriously erode the power of Congress. According to respondents, the President has the power to dictate the outcome of administrative rulemakings, even where Congress has expressly delegated legislative authority to a cabinet officer and set strict parameters within which the officer may act. There are a number of flaws in respondents' argument, which require its rejection by this Court.

To begin with, no Court has ever held that the President's supervisory power is so limitless that it empowers him to direct the outcome of an administrative rulemaking. To the contrary, the Supreme Court has made it clear on a number of occasions that the President's supervisory power does not extend so far, particularly where, as here, Congress has entrusted the decisional task to a specified officer. Thus, for example, in Myers v. United States, 272 U.S. 52, 135 (1926), the Court cautioned that "there may be duties so particularly and specifically committed to the discretion of a particular officer as to raise a question whether the President may supervise or revise the officer's interpretation of his statutory duty in a particular case." Accord, United States ex rel. Accardi v. Shaughnessy, 347 U.S. 260, 267 (1954)("if the word 'discretion' means anything in a statutory or administrative grant of power, it means that the recipient must exercise his authority according to his own understanding and conscience"); cf. Youngstown Sheet and Tube Co. v. Sawyer, 343 U.S. 579, 587 (1952)("The President's power to see that the laws are faithfully executed refutes the idea that he is to be a lawmaker").

This line of authority is bolstered by a series of Attorney General opinions dating back one hundred and fifty years. See, e.g., 1 Op. Atty. Gen. 624, 625 (1823)("If the laws, then, require a particular officer by name to perform a duty, not only is that officer bound to perform it; but no other officer can perform it without a violation of the law; and were the President to perform it, he would not only not be taking care that the laws were faithfully executed, but he would be violating the law himself."); 18 Op. Atty. Gen. 31, 33 (1884)("It has repeatedly been held that the observance of your constitutional duty of taking care that the laws be faithfully executed does not itself warrant your taking part in the discharge of duties devolved by law upon an executive officer."); see also 19 Op. Atty. Gen. 686 (1890); see generally Rosenberg, supra, 80 Mich. L. Rev. at 204.

While respondents cite a number of cases to support their theory of Executive Branch supremacy in regulatory matters, the authorities they rely on are far narrower in scope than respondents contend. Thus, Sierra Club v. Costle, the case on which respondents' most heavily rely, does not support their position. There, this Court approved OMB's role in the EPA's development of regulations to implement the Clean Air Act. But the decision in fact undercuts respondents' argument because the Clean Air Act expressly provided for OMB - EPA consultation. 657 F.2d at 393-94 n.464. If, as respondents contend, Congress implicitly authorized OMB involvement in rulemaking every time it passed a statute which did not expressly forbid OMB from playing a role, there would have been no reason for Congress to specifically include such a provision in the Clean Air Act. To imply a decision-making role for OMB when the OSH Act withheld such authority is to disregard Congress' will and "disrepects the whole legislative process." Youngstown Sheet and Tube Co. v. Sawyer, supra, 343 U.S. at 609 (Frankfurter, J., concurring).

The removal cases relied on by respondents, such as Kalaris v. Donovan, 697 F.2d 376 (D.C. Cir. 1983) and NTEU v. Reagan, 663 F.2d 239 (D.C. Cir. 1981), likewise do not stand for the broad proposition concerning the President's supervisory authority which respondents' claim. On the contrary, the cases simply reaffirm the well-settled rule that the President's removal authority extends to virtually all executive branch officers, but neither case establishes the right of the President to interfere with an executive officer's congressionally delegated decisional responsibility.[2]

Respondents' argument also overlooks the fact that, at least in this case, there is a head-on collision between Congress' command in the OSH Act and the Executive Order that OMB sought to implement. On the one hand, the OSH Act requires the Secretary of Labor to place worker protection above all other considerations in formulating health and safety standards, constrained only by the feasibility of imposing a standard. 29 U.S.C. § 655(b)(5); ATMI v. Donovan, supra, 452 U.S. at 509. On the other hand, OMB's mandate under Executive Order

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[2] It should also be noted that the sole Attorney General opinion on which respondents rely, 7 Op. Atty. Gen. 453 (1885), has long been criticized, and is inapposite in any event, since it pertains to the President's authority to carry out purely executive functions. See Rosenberg, supra, 80 Mich. L. Rev. at 204 n.55.

12291 is to compel agencies to apply strict cost-benefit analysis, and OMB is directed to block the issuance of any standard which it determines not to be cost-beneficial. Historically, there has been no doubt that where a clash between the dictates of a statute and those of an Executive Order arises, the Executive Order must give way. Youngstown Sheet and Tube Co. v. Sawyer, supra. Indeed, the Executive Order itself recognizes that it may be applied "only to the extent permitted by law", § 2, and the Justice Department has conceded that this limitation is essential. Department of Justice, Office of Legal Counsel, Memorandum of 1981, reprinted in Role of OMB in Regulation, Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce, 97th Cong., 1st Sess. 486, 489 (1981)(hereinafter "Role of OMB in Regulation").

Nonetheless, OMB rejected the STEL on the ground that it violated the cost-benefit principles set forth in EO 12291. By elevating the dictates of the Executive Order over the contrary requirements of the OSH Act, respondents plainly violated the law. See, e.g., Youngstown Sheet and Tube Co. v. Sawyer, supra; National Federation of Federal Employees v. Brown, 645 F.2d 1017, 1025 (D.C. Cir. 1981). Respondents' argument -- that the ultimate decision to delete the STEL was not based on cost-benefit grounds, Resp. Br. at 88-89 -- cannot stand because it neither focuses on the key point in the decisional process, nor is credible given the history of

EtO rulemaking. Thus, prior to June 15th, OSHA had given every indication that it intended to go forward with a STEL. OSHA admits that i[illegible] June 15th deletion of the STEL was done "largely in response to the reservations expressed" by OMB, Preamble 25775 (App. 469), which were based on the cost-benefit criteria in Section 2 of Executive Order 12291. Moreover, OSHA concedes that no new evidence relating to the STEL was adduced during its extended rulemaking. App. 529. Therefore, while the December 19 memorandum was carefully drafted to avoid explicitly relying on cost-benefit grounds, it is evident that the rationale advanced by OSHA is merely a contrivance to justify OMB's June 15th decision to drop the STEL.

As a final matter, while the respondents talk in terms of the power of the President, the President and his immediate staff had nothing to do with this case. On the contrary, the decision to delete the STEL was made by unidentified, unelected, and unaccountable staff at [illegible] who have absolutely no technical competence in the highly complex fields involved in OSHA standard setting. OMB's focus is economic efficiency; it assists the President in preparing and administering the federal budget and conducts analyses of existing and proposed regulations. 31 U.S.C. § 501. It defies common-sense to argue, as do respondents, that Congress empowered OMB's economists to override the scientific, technical judgments of the Secretary of Labor and his expert staff. It is equally implausible that the Constitution compels the conclusion that OMB may properly interfere with the delegated rulemaking responsibility of OSHA in this highly complex field. Thus, the Court should reject respondents' argument that OMB has the right to "supervise" OSHA's rulemaking activity, particularly where such supervision requires OSHA to consider factors inconsistent with those Congress enumerated in the OSH Act.

B. As a fall-back argument, respondents claim that OMB did not dictate the deletion of the STEL, but rather that the Secretary of Labor independently reached that decision. Respondents argue that the June 14th Document was merely a draft and that the discussion of the STEL in the Document was only provisional. Resp. Br. at 88-89. And, as if it were dispositive, respondents represent that the Secretary never physically signed the June 14th Document. Resp. Br. at 89.

Nothing that respondents have said supports their claim that there was anything tentative about the June 14th Document. On the contrary, there are number of factors which point inescapably to the conclusion that as of June 14th, the Department of Labor had reached a decision to go ahead with a STEL and that its decision was overridden by OMB.

First, the Department was under a court order requiring it to issue a final standard by June 15, 1984, and Judge Parker had made it clear that no further delay would be permitted. Accordingly, it is hardly credible that respondents' had not reached a final determination about a major segment of the standard just twenty-four hours before the deadline for issuing a final rule.

Second, it is equally implausible that a draft regulation of this importance would be submitted to OMB without the prior clearance of the Secretary of Labor. Respondents do not appear to contest this, but argue instead that the Document was still a "draft" because it was not yet formally signed by the Secretary. That assertion not only elevates form over substance, but is meaningless since the Executive Order prohibited the Secretary from signing the document until OMB had approved it for publication. EO 12291, § 2(F)(1). The key point, which respondents do not rebut, is that the Secretary of Labor had approved the June 14th Document, and that, but for OMB's intervention, the STEL would have been included in OSHA's final EtO standard.

Third, while respondents appear to argue that OMB's review took place in the space of only a day or so, see Resp. Br. at 89, in point of fact the June 14th Document was the end-product of a lengthy dialogue between the agencies. As OMB's June 14th letter acknowledges, OMB had been working on OSHA drafts "for weeks" prior to June 14th (App. 415), and, as OSHA documents make clear, the agency had altered at least the STEL provision of its draft in an attempt to accomodate OMB's concerns. See Memorandum from Dr. Robert Beliles to Dr. Leonard Vance dated June 13, 1984 (protesting changes in the STEL provisions made at OMB's direction)(A copy of the memorandum appears at Page A13 in the Addendum to this Brief). From this sequence, and in light of the court-ordered June 15th deadline, the only reasonable conclusion is that the June 14th Document represents the agency's final work product. Indeed, OMB obviously thought that the June 14th Document was in final form, since OMB's June 14th letter repeatedly refers to OSHA's June 14th Document as a "final rule." (App. 415).

Fourth, respondents' argument asks this Court to shut its eyes to political reality. Respondents suggest that the Secretary of Labor was simply free to ignore OMB's objections, and could go ahead with a STEL provision if he so chose. Not only was that option explicitly foreclosed by the Executive Order, but in hearings before Congress in 1982 OMB Office of Information and Regulatory Affairs Director Christopher DeMuth admitted that OSHA is not free to go ahead and implement a regulation where OMB has disapproved it under the Executive Order. _Office of Management and Budget Control of OSHA Rulemaking: Hearings Before a Subcomm. of the House Comm. on Gov't Operations_, 97th Cong., 2d Sess. 350 (1982); _see also_ Olson, _supra_, 4 Va. J. Nat. Resources L. at 42-46 (collecting illustrations of OMB's having exercised _de facto_ veto power over rulemakings). As former OMB Deputy Director James Miller put it, "[i]f you're the toughest kid on the block, most kids won't pick a fight with you. The executive order [12291] establishes things quite clearly." "Deregulation HQ," _Regulation_, at 19 (March/April 1981), _reprinted in Role of OMB in Regulation_, _supra_, at 216.[3]

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[3] Any suggestion that this case is an isolated instance of OMB's interference with OSHA rulemakings is undercut by the fact that, according to press accounts, OMB has recently blocked the issuance of a major OSHA safety rule on cost-benefit grounds. _See The Washington Post_, A19 (July 11, 1985). _See also_ Brief of _Amici Curiae_ Representative Dingell, _et al._, citing examples.

Finally, to show that the Secretary independently determined to drop the STEL, respondents point to the fact that only the STEL was deleted even though OMB had objected to other features of the standard as well, including the 1 ppm PEL. This argument is entirely without force because it overlooks the fact that the major focus of industry concern was not the PEL but rather the STEL. As petitioners demonstrated in their brief in opposition to the Association of Ethylene Oxide User's motion for a stay (pp. 9-10 & n.5), the 1 ppm PEL had extraordinarily broad support among the industry participants; in contrast, the STEL was the the chief point of controversy. Since, as we have established, OMB was simply parroting the concerns of industry, see Pet. Br. at 54 n.14, it is hardly surprising that the STEL was at the core of OMB's objections. Thus, the fact that the STEL alone was deleted does not support respondents' contention that it was the Secretary, and not OMB, that made the decision to delete it from the final standard. On the contrary, it bolsters petitioners' view that industry, through OMB, was calling the shots.

* * *

In sum, despite respondents' efforts to obscure or to avoid altogether the essential facts, it is clear that as of June 14, OSHA was prepared to issue a standard with a STEL. It is equally clear that OSHA did not do so because OMB objected to the STEL on cost-benefit grounds. By succumbing to OMB's pressure, respondents violated the OSHA statute by relinquishing the decisional responsibility entrusted by Congress to the Secretary of Labor alone, and by allowing cost benefit considerations to govern the outcome of an OSHA rulemaking. For these reasons, the Secretary's deletion of the STEL was unlawful and should be set aside.

CONCLUSION

For the reasons stated above and in petitioners' opening brief, the decision to delete the short-term exposure limit for EtO should be set aside, and the Secretary should be required to issue a short-term exposure limit, no greater than 10 ppm over 15 minutes, to govern worker exposure to ethylene oxide.

Respectfully submitted,

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Attorneys for Petitioners

July 12, 1985

ADDENDUM

EDITOR'S NOTE:

THE FOLLOWING PAGES WERE POOR HARD COPY AT THE TIME OF FILMING. IF AND WHEN A BETTER COPY CAN BE OBTAINED, A NEW FICHE WILL BE ISSUED.

#1442

MAR 1 9 1985

Mr. Robert Rowland
Assistant Secretary for
  Occupational Safety and Health
U. S. Department of Labor
Washington, D.C. 20210

Dear Mr. Rowland:

This is in response to your letter of December 21, 1984, requesting that NIOSH give special consideration to funding a study proposed by Dr. Janet Yager to determine whether short-term high level exposures to ethylene oxide (EtO) are more hazardous than an equivalent dose spread evenly over an 8-hour workday.

Dr. Yager's grant proposal to NIOSH was withdrawn because of administrative policies at the University of California, Berkeley, and has not been resubmitted.

NIOSH evaluation of the available data formed the basis for my testimony provided at the public hearings on EtO in June of 1984. Additional analysis of the data and issues surrounding this point were provided by Dr. Elliott S. Harris, Deputy Director of NIOSH, in a letter to you dated July 18, 1984. In each of these documents NIOSH recommended that OSHA adopt a limit on short-term exposures to EtO. Thus while we appreciate the implications of work such as that proposed by Dr. Yager, we do not believe that it is necessary for promulgation of an EtO standard that includes a limit on short-term exposures.

As I described in my testimony, NIOSH has concluded that the majority of occupational exposures to EtO occur over relatively short-term periods at relatively high concentrations. Therefore, I again take this opportunity to reiterate my previous recommendation that OSHA adopt a short-term limit on exposures to EtO. I believe that there is sufficient evidence on which to base such a limit. I will be happy to discuss this issue with you should you have any questions.

Sincerely yours,

J. Donald Millar, M.D.
Assistant Surgeon General
Director

cc:
R. Lemen

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CDC:NIOSH:DSDTT:lfMAZZUCKELLI:clm:Cinti.

Thus, OSHA preliminarily concludes that it is possible to produce low benzene-containing liquids containing less than 0.1 percent benzene for the solvent users. Therefore, it is technically feasible for the solvent users to comply with the standard by switching to solvents with low benzene concentration.

Short Term Exposure Limit

OSHA's contractor, JRB, (Ex. No. 153), has analyzed the efficiencies of the engineering controls and work practices discussed above, and has determined that the same controls and work practices which will reduce 8-hour TWA's to below the 1.0 ppm level will also be effective in reducing 15-minute STEL's to below the 5.0 ppm level. JRB was able to find only two operations - some maintenance activities and the loading of pure benzene -- where meeting the proposed 5.0 ppm STEL may not be possible with engineering controls. In these situations the use of respiratory protection will achieve compliance. OSHA solicits additional information on these operations. Further discussion of the STEL is discussed in section X.

EXPOSURE MONITORING

This provision of the proposed standard would require employers to determine whether any employee may be exposed to airborne concentrations of benzene. Measurements would be made by monitoring the breathing zone of one representative employee over an 8-hour period for each job classification and for each shift. OSHA infeasible (i.e., during maintenance operations) or when benzene is used in the workplace less than 30 days per year. This approach increases the performance orientation of the standard and is intended to promote expanded discussion of the proper mix of engineering control requirements with other control techniques.

OSHA believes that the industrial hygiene, monitoring and medical provisions will provide substantial but not complete additional protection for employees exposed between 1.0 ppm and 0.5 ppm. They will result in less exposure to employees through training, protective clothing and hygiene facilities, and the medical provisions will detect some abnormal blood conditions early, making it possible to reduce any remaining possible incidence of leukemia and aplastic enemia.

For the above reasons, OSHA is proposing the 1.0 ppm permissible exposure limit with a 0.5 ppm action level as needed to reduce substantially a significant risk of leukemia and other diseases and as technically and economically feasible. It will of course, consider all evidence presented in the rulemaking on issues presented including alternate exposure limits.

As discussed in Section VI, short term exposures at relatively low levels have caused chromosomal damage in animals. Those include 28 ppm for 4 hours (Tice et.al., 1982), (Ex. No. 159-88) 10 ppm for 6 hours (Kligerman, 1984) (Ex. No. 159-47) and 6 ppm for two 8-hour exposures (Gad El-Karim et.al., 1982) (Ex. No. 159-32). This and other health evidence leads OSHA to conclude preliminarily that the

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proposed short term exposure limit of no more than 5 ppm in any 15 minute period is needed. As discussed in the JRB report, it appears to be feasible. OSHA is aware that its recent decision not to promulgate a STEL for EtO has aroused debate about the appropriate circumstances requiring a STEL for any chemical. OSHA has encouraged continuation of that debate in the document.

X. Summary and Explanation of the Proposed Standard.

OSHA believes that the proposed requirements set forth in this notice are those, based on currently available data, which are necessary and appropriate to provide adequate protection to employees exposed to benzene. In the development of this proposal, OSHA has carefully considered the input from interested parties given in response to the Request for Information. In addition, numerous reference works, journal articles, and other data, including the previous benzene docket and other data accumulated by OSHA since the initiation of this preceding have been taken into consideration in the development of this proposed standard.

Scope and Application; Paragraph (a).

The proposed standard is to apply to all occupational exposures to benzene with the specific exceptions set forth in the scope and application paragraph. The risk from benzene is, of course, dependent on the degree of exposure and not on the segment of industry where the employee may be employed. However, in some segments and operations, exposures are consistently below the action

Information and Training. Every spill or leak does not automatically constitute an emergency situation. The exposure to employees must be high and unexpected. This is a performance oriented provision relying on judgement. It is not possible to specify detailed circumstances which constitute an emergency.

"Employee exposure" is defined as that exposure to airborne benzene which would occur if the employee were not using respiratory protective equipment. This definition is consistent with OSHA's previous use of the term "employee exposure" in other health standards.

Permissible Exposure Limit: Paragraph (c). OSHA proposes to revise the permissible exposure limit (PEL) for benzene by amending the current 10 ppm standard contained in 29 CFR 1910.1000, Table Z-2, which also contains an "acceptable ceiling concentration" of 25 ppm and an "acceptable maximum peak concentration" of 50 ppm to apply only where the new standard is not applicable. OSHA proposes to replace these values for most industry segments with an 8-hour time-weighted average Permissible Exposure Limit to airborne concentrations of benzene of 1 ppm and a Short Term Exposure Limit of 5 ppm, for 15 minutes as set forth in paragraph (c) of 1910.1028. This proposed PEL is based on underlying findings by OSHA that occupational exposure to benzene under current permissible exposure levels presents a significant risk to employees and that the new standard will achieve a significant reduction in that risk.

The basis for the proposed permissible 8 - hour exposure limit is discussed above in the sections on significant risk, feasibility and choice of proposed exposure limit.

OSHA has been reviewing the scientific principles concerning whether a short term exposure limit (STEL) should be set for a chemical substance. In its recent evaluation of ethylene oxide (EtO) on STEL issues (50 FR 64, January 2, 1985), OSHA received a number of comments on this issue. (See ethylene oxide OSHA Docket No. H-200, Ex. No. 168.) The following examples illustrate some of the concerns expressed in making the determination for the necessity of a STEL with regard to EtO. The American Industrial Hygiene Association (AIHA) stated:

> The selection of regulated STEL should not be an arbitrary multiple of the TWA exposure limit but rather should aim at preventing such other adverse effects not otherwise prevented by the TWA PEL alone. The two most common examples of such other effects are (1) a disproportionate increase in responses for excursion doses above the TWA (i.e., nonlinear effects) or (2) the onset of an acute response not important near the TWA (e.g., acute irritation versus chronic damage) (Ex. No. 164M).

The American Academy of Industrial Hygiene stated that it would favor the use of a STEL for EtO in conjunction with a PEL of 1 ppm (as an 8 hr TWA) if either of the following questions could be answered affirmatively:

> Does EtO lead to significant acute effects or irritation during brief transients of high exposure encountered in workplaces where a PEL of 1 ppm is being met? (2)Does damage to the receptor (DNA), which is presumed to increase the likelihood of chronic or delayed disease, follow

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> nonlinear kinetics between dose of EtO and response and, thereby, weight more heavily the transient high exposures? (Ex. No. 164D)

The National Institute for Occupational Safety and Health (NIOSH) also discussed the means for determining whether or not a STEL for a substance is necessary. It stated:

> ...there are two concepts that must be explored. The first concept is practicality; the second is necessity... the practicality of a short term exposure limit can be described by examination of how workers are most likely to be exposed and whether or not their exposure can be reasonably controlled...the issue of the necessity of a short term exposure limit centers on the identification and prevention of adverse health effects. (Ex. No. 164J)

NIOSH made the latter statement in the context that the empirical observation of adverse health effects as a result of short term exposure should constitute the necessity for OSHA to adopt a STEL in order to contain such exposures. The National Institute of Environmental Health Sciences' approach for determining the need for a STEL for a toxic substance was similar to that of NIOSH, i.e., short term levels should be controlled if dose received in such a manner is associated with adverse health effects (Ex. No. 164J)

OSHA seeks comment on the scientific principles it should use to determine the necessity for incorporating a STEL as part of a permissible exposure limit for a toxic substance.

With regard to a STEL and benzene specifically, Irons of the Chemical Industry Institute of Toxicology recently presented study results on benzene and stated:

> ...our experimental evidence would highlight a concern that has been focused recently on transient exposure in the occupational environment rather than continuous low level exposure... where transient exposure is more important with respect to the individual than constant exposure to some low level or a time weighted average (Ex. No. 159-41A).

In a previous study, Irons had determined that the polyphenolic metabolites of benzene, primarily hydroquinone and catechol, appear to be responsible for benzene immune suppression and bone marrow suppression. Thus, separate mice were administered hydroquinone or catechol both on an intermittent basis and continuously.

Irons stated:

> We found if we took the same dose of hydroquinone that we were giving repeatedly for a continuous regimen and gave it for three days and allowed the animals four days to recover, then gave it again, an intermittent exposure, so that over a 30 day period, for example, the animals are receivng approximately 45% of the dose they would have received with continuous exposure, and we have a very pronounced drop in bone marrow cellularity, we have a decrease, a progressive decrease in circulating white counts, primarily associated with the lymphocytes, we have a progressive decrease in erthrocytes, circulating erythocyte counts. We have followed these animals now out to approximately between 6 and 8 weeks. They're beginning to drop dead.... with what would be considered a classic aplastic response or aplasia in bone marrow. (Ex. No. 159-41A).

With repeated administration of the metabolites, only a transient effect which gradually returned to normal was observed. On the basis of these observations, Irons concluded

> ...intermittant exposure appears to be much more potent at producing bone marrow effects than is continuous exposure, and it may be that protection of the worker in an occupational setting requires prevention of peak exposures rather than the progressive lowering of the TWA in the absence of regulating or limiting transient exposure situations.

Although two cohort studies of refinery workers did not demonstrate a significantly elevated increased risk of death from leukemia, two case-control studies of leukemia deaths among these cohorts of refinery workers have significantly associated the deaths with specific benzene exposure jobs (Rushton and Alderson, 1981) or with a history of longest employment as general pipefitters (RR=2.7), maintenance and yard pipefitters (RR=2.8), or in utilities (RR=4.6) (Divine and Kaplan, 1983). The mode of benzene exposure in these latter jobs is considered to be through intermittent bursts as pipefitters and utility personnel usually have major responsibilities for repairing broken pipes or leaking seals in streams that may contain from 5% to 100% benzene. Given the limited statistical sensitivity of the case-control studies and yet the identification of a significant association between dying from leukemia and the mode of benzene exposure that may have been experienced by these workers, one could argue that short-term intermittent bursts of benzene may have been more of a factor than continuous low level exposure among these workers. On the other hand, lower elevated relative risks of leukemia that might be associated with general low level exposure may not have been identified because of limited statistical sensitivity.

In the study by Wong (Ex. No. 151A) which demonstrated a dose-response relationship between cumulative benzene exposure and death from lymphatic and hematopoietic cancer, a relative risk of 3.4 was observed for those persons categorized as having experienced maximum peak benzene exposures below 25 ppm. (See more detailed review of the study in section dealing with epidemiologic study results.)

DOW Chemical Company submitted a report to EPA and to NIOSH shortly after the earlier OSHA administrative record on benzene closed in 1978 (Holder, 1978, Ex. No. 159-49). This study demonstrated signficantly elevated chromosomal breakage in circulating lymphocytes among 52 workers employed in operations where 8-hour time weighted average benzene concentrations ranged between 2-10 ppm. Peak levels of benzene associated with the TWA concentrations as determined by 2-3 minute sampling periods ranged from 50 to greater than 100 ppm. Ceiling concentrations as determined by 15-minute sampling periods were reported to have been 25 ppm (Holder, 1978, Ex. 159-49). Further analyses by level of exposure indicated elevated chromosomal damage at exposures averaging below 1.0 ppm, as well as a dose-response relationship between chromosomal damage and benzene exposure (Picciano, 1980). Although the frequency of peaking is unknown, Holder implied that the chromosomal damage was due to the peak exposures (Holder, 1978, Ex. 159-49).

OSHA seeks comment on whether intermittent peak exposures to benzene carry any greater risk of disease than continuous low level exposures and whether such a determination can or should be based on either experimental data or epidemiologic findings.

With further regard to the STEL issue, OSHA has preliminarily determined that the 1 ppm TWA may not eliminate the significance of cancer risk. Thus, a 5 ppm STEL, which the Agency has determined to be feasible would further reduce the risk for those segments of industry where workers receive their benzene dose as a result of short-term bursts. OSHA seeks comments on this approach.

In summary, OSHA has noted that the proposal to lower the current PEL from 10 ppm TWA to a 1 ppm TWA is based on feasibility and on risk assessments indicating a significant risk at the current PEL and a significant reduction in risk (though the risk is still significant) by lowering the PEL to an 8-hour TWA of 1 ppm. The 5 ppm STEL is based on: (1) study indicating acute toxic effects on the bone marrow as a result of intermittent exposure in contrast to no such effect being observed as a result of a greater dose given continuously: (2)

All

the above mentioned case-control epidemiologic study results, (3) the elevated relative risk for individuals in the CMA study who experienced maximum peak benzene exposure levels below 25 ppm, and (4) analysis indicating feasibility of compliance with a 5 ppm STEL which will consequently reduce the TWA and hence further reduce the significant risk remaining at 1 ppm for those segments of industry where dose is received as a result of short-term bursts. OSHA seeks comment on whether such a determination is reasonable and appropriate.

There has been some recent suggestion that a 1 ppm PEL for benzene should be based on 40-hours instead of the usual 8-hour time weighted average. Industry representatives have made this suggestion on various occassions. The unions have expressed reservation to this approach. However, the Ministry of Labour of Ontario, Canada has adopted the 1 ppm PEL for a 40-hour time weighted average in its benzene regulation, dated November 9, 1984 (Ex. No. 162). OSHA, therefore, requests comments on this subject and ask for evidence which may or may not support such an approach.

The 1978 final standard for benzene included under the PEL section a paragraph on "dermal and eye exposure limits" which prohibited such exposures. This paragraph has not been included in this proposed standard since the requirement

U.S. Department of Labor

Occupational Safety and Health Administration
Washington, D.C. 20210

Reply to the Attention of:

MEMORANDUM FOR: R. Leonard Vance, Director
Health Standard Programs

FROM: Robert Beliles, Director RB 6/13/84
Office of Risk Assessment

Peter Infante, Director P. Infante 6/13/84
Office of Standards Review

SUBJECT: 10 ppm STEL for ETO

We are concerned with regard to the selection of 10 ppm as a STEL for ETO for the following reasons:

1. There is ample evidence in the record that 10 ppm STEL is an effect level with regard to changes in the chromosomal material induced by a short term exposure and with regard to the induction of cancer and reproductive effects at 10 ppm.

2. There is more support in the record for a STEL of 5 ppm with regard to both feasibility (technical and economic) and biological effects than for 10 ppm.

3. The selection of the 10 ppm STEL ignores the ACGIH recommendations of an excursion limit of 5 times the permissible exposure limit, if there are not sufficient data to establish the STEL at a safe level.

4. We are concerned that the 10 ppm was selected on the basis of economic considerations which is contrary to the decision of the Supreme Court in the Cotton Dust case.

5. We are aware that this change was dictated to the agency by OMB without input from OSHA health professionals. This raises concern to us not only for the ETO standard but for future standards.

CC: John Martonik